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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,516	04/27/2001	Julie E.M. McGeoch	H0498/7095 TJO	9062
7590	10/06/2003		EXAMINER OLSEN, KAJ K	
Timothy J. Oyer Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210			ART UNIT 1753	PAPER NUMBER

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/844,516	MCGEOCH ET AL.	
	Examiner Kaj Olsen	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
  - 2a) This action is **FINAL**.      2b) This action is non-final.
  - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 1-55 is/are pending in the application.
    - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
  - 5) Claim(s) \_\_\_\_\_ is/are allowed.
  - 6) Claim(s) 1-55 is/are rejected.
  - 7) Claim(s) \_\_\_\_\_ is/are objected to.
  - 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____                                     |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 27 is drawn to a method, but the claim doesn't specify what the method is.

Applicant should explicitly state in the preamble of the claim what the method is drawn to (see claim 36 for a definitive preamble).

4. In claim 28, it is unclear what is meant by oscillating "steadily". What would one possessing ordinary skill in the art reasonably construe as being a *steady* oscillation?

5. Similarly with claim 33, it is unclear what one possessing ordinary skill in the art would reasonably construe as being "stable" over a given period of time.

### *Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 1-13, 15-21, 24-31, 33-35, and 46-52 are rejected under 35 U.S.C. 102(b) as

being anticipated by Ikematsu et al (USP 5,503,744) with evidence provided by the UCSD

Transport Protein Database.

8. Ikematsu discloses a device for generating an oscillating current that comprises an insulating layer (11 or 13) positioned between two electrolyte reservoirs 12 having positive and negative biased electrodes (fig. 2). The insulating layer possesses a hole (H or the pores of the membrane) where an ion channel (i.e. a pore) is positioned in the hole (col. 4, lines 10-22). Said ion-channel opens and closes allowing and preventing communication between the reservoirs in order to generate electrical current (fig. 4).

9. With respect to the diameter of the hole, see col. 4, line 15.

10. With respect to the diameter of the pore (i.e. the ion channel), the ion channel of Ikematsu is alamethicin and the UCSD Transport Protein Database evidences that the pore of alamethicin is 8-10 Angstroms and is cation selective ion-channel.

11. With respect to the device and the oscillation frequency and current levels, these are only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. However, see col. 5, lines 44-57.

12. With respect to method claims 27-31 (those limitations not already covered above), Ikematsu discloses measuring the electrical output (col. 5, line 33 through col. 6, line 17).

13. With respect to the duration of the oscillation, because the reference anticipates all the function of the claim, then Ikematsu would inherently be capable of "steadily" oscillating for a day.

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14. With respect to the containers being fastenable to each other, the containers shown in fig. 3A-3C clearly would be capable of being fastenable to each other.

15. With respect to the use of at least two separate membranes, the currents monitored by Ikematsu would appear to come from a plurality of different ion-channel containing membranes (see also col. 7, lines 36-44).

16. Claims 25, 27-33, 36, 38-43, 45, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McGeoch et al (Brain Research 766 (1997), pp. 188-194).

17. With respect to claim 27-33, McGeoch discloses providing at least one membrane between two electrolyte reservoirs where the membrane containing ATP synthase subunit c has at least one oscillating channel, and measuring the electrical output of the channel (see fig. 2 and section 2.4 on p. 189).

18. With respect to the stability or the steadiness of the ion channel, because McGeoch is utilizing the ATP synthase subunit as some of the claims of the instant invention are drawn to, the ion-channel and protein of McGeoch inherently satisfies the claimed invention.

19. With respect to claims 36, 38-43, and 45 (those limitations not already covered above), fig. 2 shows the frequency of the ion channel response changing as a function of a sample. With respect to the particular detection levels, because McGeoch utilizes the sample ion-channel as that disclosed by the instant invention, McGeoch would be inherently capable of utilizing the set forth amount of analyte.

20. With respect to claim 46, McGeoch uses an amplifier in communication with the ion channel (section 2.4 on p. 189).

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21. With respect to claim 25 (those limitations not covered above), McGeoch discloses the use of a one micron diameter hole (section 2.4 on p. 189). Although that is not technically "less than 1 µm" as set forth by the claim, one possessing ordinary skill in the art would recognize that diameters slightly less than 1 micron would have been within the purview of one possessing ordinary skill in the art.

***Claim Rejections - 35 USC § 103***

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. Claims 1, 2, 6-24, 26, 34, 35, 47, 49-51, 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGeoch in further view of Alberts et al (Molecular Biology of the Cell, Third Edition, 1994).

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25. McGeoch set forth all the limitations of these claims but did not explicitly set forth the electrolyte reservoirs and insulating barriers of these claims. McGeoch appears to rely on conventional patch clamping techniques for measuring the oscillating currents (see section 2.4 on p. 189). Alberts teaches how conventional patch clamps can be performed. Namely, a pipette (i.e. an insulating layer) with a hole present has a cell membrane that forms across the surface of the hole where the membrane contains the ion-channel (i.e. the pore) (see fig. 4-55 and discussion accompanying it). The inside of the pipette would constitute one electrolyte container while the solutions on the other side of the pipette would be a separate electrolyte, and whatever container contains that electrolyte (e.g. beakers, etc) would constitute another electrolyte reservoir. McGeoch teaches in section 2.4 what fluids should be present in each of these reservoirs. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Alberts for the patch clamp experiments of McGeoch because the use of conventional structure for the performance of specific experiments requires only routine skill in the art.

With respect to the use of an array of holes, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize an array of holes since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

26. Claims 14, 32 and 53-55 (and claims 10-13 and 31 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikematsu in view of McGeoch.

27. Ikematsu set forth all the limitations of these claims, but did not disclose the particular use of the subunit c of ATP synthase as the oscillating protein. As discussed above, McGeoch

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disclosed this particular protein and disclosed that this protein provides the desired oscillations with a large range of oscillating frequencies (see "4. Discussion" starting on p. 193). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of McGeoch for the oscillating protein of Ikematsu because this protein has been identified as a viable candidate providing a large range of oscillating frequencies.

28. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGeoch in view of WO 97/05477 (hereafter "WO '477").

29. McGeoch set forth all the limitations of the claim, but did not specify derivatizing the ion channel with functional groups to detect a predetermined analyte. WO '477 teaches in an alternate sensor relying on ion channels that functional groups can be added to ion channels so that different analytes can be sensed with a given ion channel (p. 9, line 33 through p. 10, line 31). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '477 for the method of McGeoch in order to increase the utility of the oscillating device to other analytes.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for regular communications is (703) 305-3599 and the fax number for after-final communications is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.



Kaj K. Olsen  
Patent Examiner  
AU 1753  
September 29, 2003